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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 202952

May 29, 2003

Attn: Docket #02N-00277

Dear Sir or Madam:

I'm enclosing two copies of a letter as a comment on Section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act.

I thank you for your interest and please pass it on.

Sincerely,

Richard Ross
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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Md 20952

Attn: Docket #02N-00277

I'm writing in reference to my phone conversation with Bob Lake on Thursday, May 8,th concerning the re-tracing of bulk commodity products. After more than twenty-five years in the agricultural commodity food business, my experience is that the record-keeping aspect of "one-up, one-down" can easily be maintained for farm-to-table retracing. Although bulk commodity products, like wheat, tend to co-mingle during storage, it is possible to track the movement of these products throughout the system and limit the number of potential suppliers that may be involved in a possible investigation.

My understanding is that in the event of an investigation, the FDA's goal would be to take a potentially adulterated product and use the code date and identifiers on the package be able to start the "one-up, one-down" process to trace the products origin. In the satellite broadcast, Bob Lake used the example of a bakery. Using that example, the process would be as follows:

1. Identify and notify the baker and they would do their research
 - a. One-up - Determine the identity of the mode of transportation and Receiver of the product
 - b. One-down - Identify when the product was manufactured, what ingredients were used, their code dates and manufacturers
 - c. If using bulk products, (food grade oil, sugar, flour) determine the manufacturer(s) of these bulk products by tracking use and the timing of deliveries by the transporter.
 - d. Provide information to the FDA
2. The Receiver in 1a - tracks storage, transporter and subsequent delivery to the next receiver
Continue tracking to the point of sale
3. The bakery's ingredient manufacturers (1b) would be notified, given code dates and transporter information from the FDA.
 - a. Bagged ingredient manufacturers would have code dates, and lot number information
 - b. Bulk ingredients manufacturers, flour for example, can be traced from the flour, back to the wheat ground, the potential suppliers of the wheat and their transporters

Note: It is preferable to provide a limited list of potential wheat suppliers rather than a total list of wheat suppliers
4. The continued "One-down" process progresses to the wheat farmer or grain elevator
 - a. The farmer is exempt
 - b. The elevator is notified and they trace back the wheat from the time and date of loading the transporter through the blending process and back to the potential sources of delivery to the elevator.
 - c. Give the FDA a list of potential wheat suppliers
 - d. Continue tracking to approximate origin

According to the FDA's Guidance for Industry, agricultural commodity food businesses should "focus operator's attention sequentially on each segment of the farm-to-table system that is within their control, to minimize the risk of tampering or other malicious, criminal, or terrorist action at each segment."¹ The information needed to comply with each segment the farm-to-table system exists and should be maintained for the safety of the food supply whether it is regarding a recall of products or a bioterrorism event.

Sincerely,



Richard Ross
Ross Consulting, L.L.C.

¹ Guidance for Industry, FDA, Center for Food Safety and Applied Nutrition, March 21, 2003